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February 15, 2008

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From: Brent P. Ray

Direct Telephone No.: (312) 269-1521

JP No.: JP006602

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Send copies to:

Number of pages (including this page): 9

Re: In re: U.S. Patent No. 4,994,078

Issued: February 19, 1991

Inventor: Robert K. Jarvik

For: INTRAVENTRICULAR ARTIFICIAL HEARTS AND METHODS OF THEIR
SURGICAL IMPLANTATION AND USE

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Message: Please see attached.

Please call us immediately if the facsimile you receive is incomplete or illegible. Please ask for the facsimile operator.

PAGE 2/9 * RCVD AT 2/15/2008 4:47:54 PM (Eastern Standard Time) * SVR:USPTO-EFXRF-4/17 * DNIS:2737728 * CSID: * DURATION (mm:ss):02:34



Mary Blinder, MD
Director of Medical Affairs

PMA Document Mail Center (HFZ-401) Center for Devices & Radiological Health Food and Drug Administration 9200 Corporate Boulevard Rockville, MD 20850	PMA Shell Number: M070017 Module 1: System Engineering Sponsor, Manufacturer and Applicant: Jarvik Heart, Inc. 333 West 52 nd Street New York, New York 10019 212-397-3911 Fax 212-397-3919
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January 30, 2008

Dear Dr. Patel,

Enclosed are three (3) hardcopies of PMA Shell Number M070017, Module 1: System Engineering for the Jarvik 2000 Heart Assist System. In addition, per the instructions accessed at <http://www.fda.gov/cdrh/electsub.html>, two (2) electronic copies are provided with this submission and both copies are an exact duplicate of the original paper submission.

In addition, we are submitting the following 3 documents related to fees for your records even though we do not believe these documents are mandatory:

Eligibility for Small Business Qualification
Facility Registration
Draft Medical Device User Fee Cover Letter

Please contact me at (212) 397-3911 ext. 30 or mblinder@jarvikheart.com if you have any questions.

Sincerely,

A handwritten signature in cursive script that reads "Mary Blinder, MD".

Mary Blinder, MD

333 West 52nd Street, New York NY 10019-6238 Ph: (212) 397-3911 x30 Fax: (212) 397-3919 mblinder@jarvikheart.com

Page 1 of 2

Mary Blinder, M.D.

From: Pamela DeLaGrange [pdelagrang@jarvikheart.com]
Sent: Friday, February 01, 2008 11:28 AM
To: Dr Jarvik; 'Stuart McConchie'; 'Mary Blinder, M.D.'; 'Janine Lynch'; 'Kamal Gandhi'
Subject: FW: FedEx MPS Shipment 798864320906 Delivered

Attached is your copy of the delivery verification of the PMA Submittal to the FDA

Pamela

-----Original Message-----

From: TrackingUpdates@fedex.com [mailto:TrackingUpdates@fedex.com]
Sent: Friday, February 01, 2008 11:13 AM
To: pdelagrang@jarvikheart.com
Subject: FedEx MPS Shipment 798864320906 Delivered

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Company Name:	Jarvik Heart, Inc.
Name:	Pamela DeLaGrange.
E-mail:	pdelagrang@jarvikheart.com

Our records indicate that the following MPS shipment has been delivered:

Reference:	PMA #M070017 Module 1
Ship (P/U) date:	Jan 31, 2008
Delivery date:	Feb 1, 2008 10:24 AM
Sign for by:	M.BENJAMIN
Service type:	FedEx Priority Overnight
Packaging type:	Your Packaging
Tracking number:	<u>790929393305</u>
Delivered to:	Mailroom
Weight:	50.00 lb.
Special handling/Services:	Deliver Weekday

Tracking number:	<u>798364560110</u>
Delivered to:	Mailroom
Weight:	50.00 lb.
Special handling/Services:	Deliver Weekday

Master tracking number:	<u>798864320906</u>
Delivered to:	Mailroom
Weight:	50.00 lb.
Special handling/Services:	Deliver Weekday

Shipper Information

Recipient Information

2/1/2008

From: Origin ID: QNYA (212397-3911)
 Pamela DeLaGrange
 Janik Heat, Inc.
 333 West 52nd Street
 Room 700
 New York, NY 10019



Ship Date: 31JAN08
 ActWgt: 50 LB
 System#: 1606634/NET8011
 Account#: 8

Dimmed: 20 X 15 X 15 IN

Delivery Address Bar Code



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Ref # PMA #M070017 Module 1
 Invoice #
 PO #
 Dept #

1/3

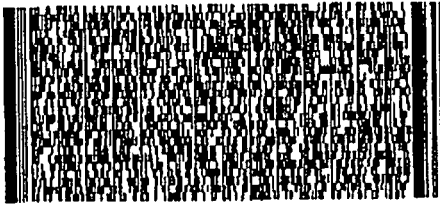
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A2

TRK# 7988 6432 0906

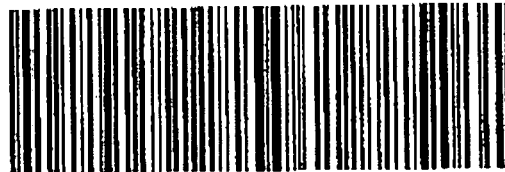
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 Pamela DeLaGrange
 Jarvis Heart, Inc.
 333 West 52nd Street
 Room 700
 New York, NY 10019



Ship Date: 31JAN08
 Act Wgt: 50 LB
 System#: 1629634/INET8011
 Account#: S

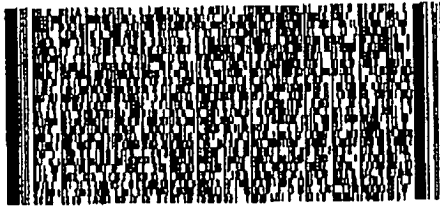
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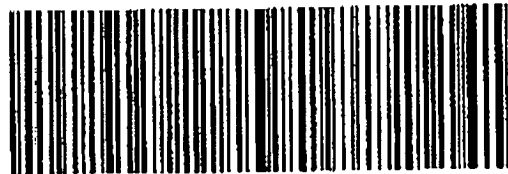
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From: Origin ID: QNYA (212)397-3911
 Pamela DeLaGrange
 JanVik Health, Inc.
 333 West 52nd Street
 Room 700
 New York, NY 10019



Ship Date: 31JAN08
 Adm Wgt: 50 LB
 System: 1609634/NET8011
 Account: S *****

Dimmed: 20 X 15 X 15 IN

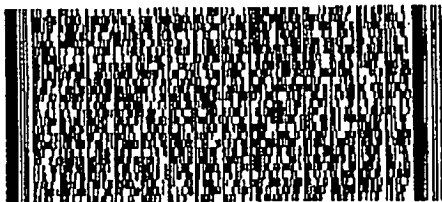
Delivery Address Bar Code



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 ROCKVILLE, MD 208503229

Ref # PMA#M070017 Module 1
 Invoice #
 PO #
 Dept #

MPS# 7983 6456 0110
 0283
 Mstr# 7988 6432 0906 0201
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Pamela DeLaGrange

From: TrackingUpdates@fedex.com
Sent: Friday, February 01, 2008 11:13 AM
To: pdelagrang@jarvikheart.com
Subject: FedEx MPS Shipment 798864320906 Delivered

This tracking update has been requested by:

Company Name: Jarvik Heart, Inc.
Name: Pamela DeLaGrange
E-mail: pdelagrang@jarvikheart.com

Our records indicate that the following MPS shipment has been delivered:

Reference: PMA #M070017 Module 1
Ship (P/U) date: Jan 31, 2008
Delivery date: Feb 1, 2008 10:24 AM
Sign for by: M.BENJAMIN
Service type: FedEx Priority Overnight
Packaging type: Your Packaging

Tracking number: 790929393305
Delivered to: Mailroom
Weight: 50.00 lb.
Special handling/Services: Deliver Weekday
Tracking number: 798364560110
Delivered to: Mailroom
Weight: 50.00 lb.
Special handling/Services: Deliver Weekday
Master tracking number: 798864320906
Delivered to: Mailroom
Weight: 50.00 lb.
Special handling/Services: Deliver Weekday

Shipper Information
Pamela DeLaGrange
Jarvik Heart, Inc.
333 West 52nd Street;Room 700
New York
US
10019

Recipient Information
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